

K961251

JUN 27 1996

510(k) SUMMARY

<i>Proprietary Name:</i>	PUNCTUR-GUARD® Winged Set
<i>Classification Name:</i>	Single Lumen Hypodermic Needle
<i>Regulation #:</i>	880.5570
<i>Class:</i>	II
<i>Panel Code:</i>	80
<i>Product Code:</i>	FMI
<i>Reason for submission:</i>	new device

This document demonstrates the substantial equivalence of the PUNCTUR-GUARD® Winged Set to currently marketed Winged Blood Collection Sets, such as the Vacutainer® Brand Blood Collection Set, reorder number 7250, manufactured by Becton Dickinson, the SurFlo® Winged Infusion Set, reorder number SV*21BLK, manufactured by Terumo, and the Butterfly® Infusion Set, reorder number 4492, manufactured by Abbott Laboratories.

This summary provides the following safety and effectiveness information upon which a determination of substantial equivalence is based.

The PUNCTUR-GUARD® Winged Set is a sterile, single use blood collection set that performs the following functions.

- (i) provides sterile vascular access for the collection of blood utilizing a vacuum tube system or syringe.
- (ii) allows vascular access with a low entry angle and firm needle tip control.
- (iii) permits collection of blood via a flexible tubing, effectively dissociating the puncture site from the proximal end of the device.

Device Description:

The PUNCTUR-GUARD® Winged Set is comprised of a sharp, lubricated stainless steel front needle which is attached to a flexible winged body. A blunt inner cannula is contained inside the front needle and provides the fluid path. A third wing is provided to actuate the blunting cannula forward of the needle point. The third wing is connected to flexible tubing at the end of which is a female luer connector. The device will be available in two configurations, with a male luer cap covering the female luer connector or with a Multi-Sample Lure Adapter (MSLA) attached to the female luer connector. The MSLA is comprised of a valved needle, hub with female luer connector and threaded section for the attachment of a holder. BIO-PLEXUS manufactures a one piece Needle Holder.

Labels and Labeling:

Labeling meets the requirements of the 21 CFR Part 801 as relates to the indications for use of the device.

Descriptive Comparison to Legally Marketed Devices:

The comparison of the intended use, technological features and specifications (including material) of the PUNCTUR-GUARD® Winged Set to currently marketed winged blood collection sets demonstrates the device's substantial equivalence. The blunting feature is compared to the PUNCTUR-GUARD® Blood Collection Needle as they utilize a similar technology.

Performance Testing:

The bench tests and the simulated use tests confirmed the similarities of the PUNCTUR-GUARD® Winged Set to the equivalent currently marketed products.

Accessories to the Device:

The PUNCTUR-GUARD® Winged Set with a MSLA is by design compatible with PUNCTUR-GUARD® Needle Holders.